

REMARKS

Specification Amendments

The Specification has been carefully checked for typos and grammatical errors. The foregoing Specification Amendments update the specification regarding the priority document, insert punctuation to clarify a sentence on page 2, insert an issued patent number to replace reference to a prior art PCT application and correct a typographical error in Example 2. In addition, the Specification Amendments insert standard headings and an abstract, as required.

Claim Amendments

Claim 2, a so-called “Swiss” claim, was included in the parent PCT application to satisfy claim requirements in some countries which do not permit patenting diagnostic methods. This claim is canceled by the foregoing Claim amendments.

Claim 1 has been extensively amended to place the claim in a more formal Jepson format, i.e. the preamble reciting the prior art method “topically applying ... suspect tissue,” followed by a recitation of “the improvement in said method ... comprising the step of topically applying ... to said locus ... acceptable solvent.”

It is believed that the claim now clearly contains antecedent basis in the preamble for “the locus”, “the rate” has been canceled, “said method” has been identified as said diagnostic method, “said stain” has been replaced by said marking agent for which there is clear antecedent basis in the amended preamble. Any indefiniteness “application” in the improvement portion of the claim refers has been clarified by prior to applying said marking agent to said locus, a clear reference back to the preamble recitation “mitochondrial marking agent.” The spelling of epithelial has been corrected.

Finally, Claim 1 has been amended to specify that the protein applied in the improvement portion of the Jepson claim is non-toxic, is amphiphillic and is applied as a solution ... in a pharmacologically acceptable solvent. Each of these limitations finds express support in the Specification, e.g., page 5, lines 15-16 and page 10, lines 19-20.

It is respectfully urged that Applicant is fully entitled to claim the use of an amphiphillic protein, rather than restricting the scope of the claim to albumin as suggested by the Examiner. The entire tenor of the disclosure is generic with respect to the use of an amphiphilic protein and considerable guidance is given as to preferred and operable sub-generic classes of the proteins, e.g., albumin, globulins, serum albumin, milk proteins, such as casein, gluten proteins, wheat albumins, prolamins and glutenins. (Specification, page 5, lines 4-14)

Further, the working examples are not limited to “albumin”, but also include globulins, casein, gluten albumin, wheat prolamins and glutenins. (Example 5, page 10)

Since the disclosure expressly supports “amphiphilic protein” and workable and preferred examples of such proteins are disclosed, it is respectfully submitted that the Specification is clearly “enabling.”


It appears that the rejection based on the scope of the term “protein” is, in reality, a “written description” rejection in “enablement” clothing. These are two clearly separate and distinct requirements of 35 USC §112. *In re Curtis*, 354 F.3d 1347, 1357 (Fed.Cir. 2004). And the present situation is certainly not the same as that in *Curtis*, where the inventor was arguing that disclosure of a species in an earlier application was a sufficient inference to satisfy the written description requirement of a genus in a later application. Applicant disclosed the genus *in haec verba* in the application as filed.

In the present application, a completely routine clinical procedure is described in Example 4, a procedure that could be straightforwardly practiced by any dentist. The question of whether there are false positives is then simply determined by subjecting stained tissue samples to normal histological examination.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully urged that this application is now in condition for allowance. Reconsideration of the rejections and objections is respectfully requested.

Respectfully submitted,



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